

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MORIMOTO *et al.*

Appl. No.: 10/584,837

Intl. Filing Date: December 28, 2004

For: **Methods of Identifying
Immunoregulatory Agents,
Immunoregulatory Agents, and
Uses Thereof**

Confirmation No. 8525

Art Unit: *To Be Assigned*

Examiner: *To Be Assigned*

Atty. Docket: 2144.0150002/RWE/RAS

Information Disclosure Statement Under 37 C.F.R. § 1.97(b)

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **NPL1** to **NPL25** are submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Date: January 11, 2007

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/584,837
				Intl. Filing Date	December 28, 2004
				First Named Inventor	Chikao MORIMOTO
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	1	of	3	Attorney Docket Number	2144.0150002/RWE/RAS

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	NPL1	BURNS, K., <i>et al.</i> , "Tollip, a new component of the IL-1RI pathway, links IRAK to the IL-1 receptor," <i>Nat. Cell Biol.</i> 2:346-351, Nature Publishing Group (2000)	
	NPL2	CHO, K.A., <i>et al.</i> , "Senescent Phenotype Can Be Reversed by Reduction of Caveolin Status," <i>J. Biol. Chem.</i> 278:27789-27795, American Society for Biochemistry and Molecular Biology (July 2003)	
	NPL3	CHRISTOPHERSON, K.W., <i>et al.</i> , "Suppression or Deletion of CD26 (DPPIV) Activity on Donor Cells Greatly Enhances the Efficiency of Mouse Hematopoietic Stem & Progenitor Cell Homing and Engraftment <i>In Vivo</i> ," <i>Blood</i> 102:38a, American Society of Hematology (November 2003)	
	NPL4	ELLIOTT, M.H., <i>et al.</i> , "Cholesterol-Dependent Association of Caveolin-1 with the Transducin α Subunit in Bovine Photoreceptor Rod Outer Segments: Disruption by Cyclodextrin and Guanosine 5'-0-(3-Thiotriphosphate)," <i>Biochemistry</i> 42:7892-7903, American Chemical Society (July 2003)	
	NPL5	HO, L., <i>et al.</i> , "In Vitro and in Vivo Antitumor Effect of the Anti-CD26 Monoclonal Antibody 1F7 on Human CD30+ Anaplastic Large Cell T-Cell Lymphoma Karpas 299," <i>Clin. Cancer Res.</i> 7:2031-2040, The American Association for Cancer Research (2001)	
	NPL6	IKUSHIMA, H., <i>et al.</i> , "Internalization of CD26 by mannose 6-phosphate/insulin-like growth factor II receptor contributes to T cell activation," <i>Proc. Natl. Acad. Sci. USA</i> 97:8439-8444, National Academy of Sciences (2000)	
	NPL7	IWATA, S., <i>et al.</i> , "CD26/dipeptidyl peptidase IV differentially regulates the chemotaxis of T cells and monocytes toward RANTES: possible mechanism for the switch from innate to acquired immune response," <i>Int. Immunol.</i> 11:417-426, The Japanese Society for Immunology (1999)	
	NPL8	KAMEOKA, J., <i>et al.</i> , "Direct Association of Adenosine Deaminase with a T Cell Activation Antigen, CD26," <i>Science</i> 261:466-469, American Association for the Advancement of Science (1993)	
	NPL9	MARELLA, M., <i>et al.</i> , "Filipin Prevents Pathological Prion Protein Accumulation by Reducing Endocytosis and Inducing Cellular PrP Release," <i>J. Biol. Chem.</i> 277:25457-25464, American Society for Biochemistry and Molecular Biology (July 2002)	
	NPL10	MARTIN, M.U., <i>et al.</i> , "Summary and comparison of the signaling mechanisms of the Toll/interleukin-1 receptor family," <i>Biochim. Biophys. Acta</i> 1592:265-280, Elsevier Science B.V. (November 2002)	

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known			
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		Intl. Filing Date	December 28, 2004		
		First Named Inventor	Chikao MORIMOTO		
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Sheet	2	of	3	Attorney Docket Number	2144.0150002/RWE/RAS

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	NPL11	MIZOKAMI, A., <i>et al.</i> , "Increased Population of High Fluorescence 1F7 (CD26) Antigen on T cells in Synovial Fluid of Patients with Rheumatoid Arthritis," <i>J. Rheumatol.</i> 23:2022-2026, Journal of Rheumatology Publishing Company (1996)	
	NPL12	MORIMOTO, C., <i>et al.</i> , "1F7, A Novel Cell Surface Molecule, Involved in Helper Function of CD4 Cells," <i>J. Immunol.</i> 143:3430-3439, American Association of Immunologists (1989)	
	NPL13	MORIMOTO, C., <i>et al.</i> , "The structure and function of CD26 in the T-cell immune response," <i>Immunol. Rev.</i> 161:55-70, Munksgaard (1998)	
	NPL14	NOMURA, R., <i>et al.</i> , "Tyrosine-phosphorylated Caveolin-1: Immunolocalization and Molecular Characterization," <i>Mol. Biol. Cell</i> 10:975-986, American Society for Cell Biology (1999)	
	NPL15	OHNUMA, K., <i>et al.</i> , "Soluble CD26/Dipeptidyl Peptidase IV Induces T cell Proliferation Through CD86 Up-Regulation on APCs," <i>J. Immunol.</i> 167:6745-6755, American Association of Immunologists (2001)	
	NPL16	OHNUMA, K., <i>et al.</i> , "CD26 up-regulates expression of CD86 on antigen-presenting cells by means of caveolin-1," <i>Proc. Natl. Acad. Sci. USA</i> 101:14186-14191, National Academy of Sciences (2004)	
	NPL17	SOONG, G., <i>et al.</i> , "Selective recruitment of toll like receptor components mediates airway epithelial responses to bacteria," <i>FASEB J.</i> 17:A655, The Federation of American Societies for Experimental Biology, Abstract No. 405.5 (April 2003)	
	NPL18	SUNAGA, N., <i>et al.</i> , "RNAi-mediated knockdown of caveolin-1 and c-myc leads to growth inhibition of human tumor cells," <i>Proc. Am. Assoc. Cancer Res.</i> 44:192-193, American Association for Cancer Research (July 2003)	
	NPL19	TANAKA, T., <i>et al.</i> , "Cloning and Functional Expression of the T Cell Activation Antigen CD26," <i>J. Immunol.</i> 149:481-486, The American Association of Immunologists (1992)	
	NPL20	TANAKA, T., <i>et al.</i> , "The costimulatory activity of the CD26 antigen requires dipeptidyl peptidase IV enzymatic activity," <i>Proc. Natl. Acad. Sci. USA</i> 90:4586-4590, National Academy of Sciences (1993)	

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	NPL21	TANAKA, T., <i>et al.</i> , "Enhancement of antigen-induced T-cell proliferation by soluble CD26/dipeptidyl peptidase IV," <i>Proc. Natl. Acad. Sci. USA</i> 91:3082-3086, National Academy of Sciences (1994)	
	NPL22	TORIMOTO, Y., <i>et al.</i> , "Biochemical Characterization of CD26 (Dipeptidyl Peptidase IV): Functional Comparison of Distinct Epitopes Recognized by Various Anti-CD26 Monoclonal Antibodies," <i>Mol. Immunol.</i> 29:183-192, Pergamon Press (1992)	
	NPL23	TRIGATTI, B.L., <i>et al.</i> , "Identification of Caveolin-1 as a Fatty Acid Binding Protein," <i>Biochem. Biophys. Res. Commun.</i> 255:34-39, Academic Press (1999)	
	NPL24	VOLPE, F., <i>et al.</i> , "The IL1 receptor accessory protein is responsible for the recruitment of the interleukin-1 receptor associated kinase to the IL1/IL1 receptor I complex," <i>FEBS Lett.</i> 419:41-44, Elsevier Science B.V. (1997)	
	NPL25	PCT International Search Report for International Application No. PCT/JP2004/019846, European Patent Office, Netherlands, mailed on August 3, 2005	

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